declared between the instant application and U.S. Patent No. 6,063,768 to First, issued May 16, 2000 (the '768 patent). (See 37 C.F.R. § 1.607(a)(1).)

Applicant proposes as a count of the interference sought to be declared the following:

> A method for treating neurogenic inflammation comprising, administering a therapeutically effective amount of *Clostridium botulinum* toxin to antagonize the action of at least one neurogenic inflammatory mediator, whereby said toxin interrupts a neurogenic pathway associated with said neurogenic inflammation.

(See 37 C.F.R. § 1.607(a)(2).)

Claim 1 of the '768 patent corresponds exactly to the proposed count. (See 37 C.F.R. § 1.607(a)(3).)

The newly-added claim 17 of the instant application (see "IN THE CLAIMS", above) corresponds exactly to the proposed count, and is identical to claim 1 of the '768 patent. (See 37 C.F.R. § 1.607(a)(4); 37 C.F.R. § 1.607(c).) Newly-added claims 18-22 of the instant application are identical to claims 2-6, respectively, of the '768 patent.

Support for this newly-presented claim 17 is found in the specification. (See 37 C.F.R. § 1.607(a)(5).) "[C]hemodenervative pharmaceuticals such as botulinum toxin...are effective anti-inflammatory agents." (Second paragraph of "Summary of Invention".) "[A]nti-inflammatory action is explained by resultant blockage of mast cell and nerve cell release of histamine and other preformed mediators which result in vascular dialation, increased permeability, altered sensory experience, edema and erythema." (Third paragraph of "Summary of Invention".) "The subject anti-inflammatory agent's unique property relates to the suppression of the component for the inflammatory response which occurs rapidly, and which is mediated by neural reflex mechanisms." (Sixth paragraph of "Summary of Invention".) "[I]nflammation in

torticollis in peripheral tissues may be neurogenically mediated." (Third paragraph of "Spasmodic Torticollis".) Additional detailed support for newly presented claim 17 is found throughout the specification.

As this newly-presented claim is present in the application before one year after the issuance of the '768 patent, applicant is not required to explain how the requirements of 35 U.S.C. § 135(b) are met. (See 37 C.F.R. § 1.607(a)(6).)

Applicant hereby requests that examination of the instant application be conducted with "special dispatch." (37 C.F.R. § 1.607(b)). Applicant is aware that because the instant application is not entitled to an effective filing date three months or less after the effective filing date of the '768 patent, applicant must make a *prima facie* showing of entitlement to judgment under 37 C.F.R. § 1.608(b). Applicant intends to file evidence relevant to such a *prima facie* showing as soon as is practicable, and respectfully requests that the examination of the instant application proceed with special dispatch even in the interim.

Submission of Information Disclosure Statement

Applicant submits herewith the enclosed PTO Form-1449 Information Disclosure Statement pursuant to 37 C.F.R. § 1.97(b) (see M.P.E.P § 609(B)(1)). In light of the fact that applicant has not yet received any Office Action on the merits of the instant application, applicant believes that no fee is required for the submission of this Information Disclosure Statement. However, in the event that an Office Action on the merits has been mailed, but not yet received by the applicant, applicant hereby authorizes the Commissioner to charge the required fee of $180 to Deposit Account Number 13-3250, Order No. 33677-00000, pursuant to 37 C.F.R. § 1.197(c)(2) and 37 C.F.R. § 1.17(p) (see M.P.E.P. § 609(B)(2)).

Applicant submits herewith complete copies of each cited reference, except that at

the present the following subset of references listed in the IDS is submitted only in abstract form.

Applicant apologizes for this inconvenience, and will submit full copies of this subset of references as soon as is practicable.

References Presently Submitted Only As Abstracts

Buzzi, M.G., et al., Neurogenic model of migraine, *Cephalalgia* 1995; 15(4):277-80.

Moskowitz, M.A., et al., Neuroeffector functions of sensory fibres: implications for headache mechanisms and drug actions, *J Neurol 1991; 238 Suppl 1:S18-22.*

Soter, N.A., et al., Release of mast-cell mediators and alterations in lung function in patients with cholinergic urticaria, *N Engl J Med 1980 Mar 13; 302(11):604-8.*

Levine, J.D., et al., Intraneuronal substance P contributes to the severity of experimental arthritis, *Science 1984 No 2; 226(4674):547-9.*

Lassen, L.H., et al., Histamine induces migraine via the H1-receptor. Supoort for the NO hypothesis of migraine, *Neuroreport 1995 Jul 31; 6(11):1475-9.*

Buzzi, M.G., et al., 5-Hydroxytryptamine receptor agonists for the abortive treatment of vascular headaches block mast cell, endothelial and platelet activation within the rat dura mater after trigeminal stimulation, *Brain Res 1992 Jun 26; 583(1-2):137-49.*

Dimitriadou, V., et al., Ultrastructural evidence for neurogenically mediated changes in blood vessels of the rat dura mater and tongue following antidromic trigeminal stimulation, *Neuroscience 1992; 48(1):187-203.*

Dimitradou, V., et al., Trigeminal sensory fiber stimulation induces morphological changes reflecting secretion in rat dura mater mast cells, *Neuroscience 1991; 44(1):97-112.*

Kokumai, S., et al., Effect of capsaicin as a neuropeptide-releasing substance on sneezing reflex in a type I allergic animal model, *Int Arch Allergy Immunol 1992; 98(3):256-61.*
Takeda, N., et al., Neurogenic inflammation in nasal allergy: histochemical and pharmacological studies in guinea pigs. A review, *Acta Otolaryngol Suppl 1993; 501:21-4.*

Kellogg, D.L., et al., Cutaneous active vasodilation in humans is mediated by cholinergic nerve cotransmission, *Circ Res 1995 Dec; 776(6)1222-8.*

Meijer, F., et al., Nitric oxide plays a role as mediator of conjunctival edema in experimental allergic conjunctivitis, *Exp Eye Res 1996 Apr; 62(4):359-65.*

Wang, Z.Y., et al., The contribution of nitric oxide to endotoxin-induced ocular inflammation: interaction with sensory nerve fibres, *Br J Pharmacol 1996 July; 118(6):1537-43.*

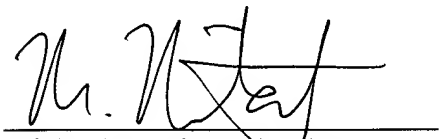
Fees

Applicant recognizes that the instant application, as amended, contains 23 total claims, thus requiring payment of a fee of $27, which represents the small-entity fee of $9 per claim in excess of 20. Applicant also recognizes that the instant application, as amended, contains one additional independent claim, thus requiring payment of the small-entity fee of $40. The Commissioner is hereby authorized to charge the total of $67 in claim fees to Deposit Account Number 13-3250, Order No. 33677-00000. In the event that additional claim fees are required, the Commissioner is hereby authorized to charge such fees to Deposit Account Number 13-3250, Order No. 33677-00000.

No extension of time is believed necessary for this filing. However, any extension of time which may be required for this filing is hereby petitioned for. The Commissioner is authorized to charge any extension of time or other fees which may be required for this paper to Deposit Account Number 13-3250, Order No. 33677-00000.

An examination on the merits of the instant application with special dispatch is respectfully requested.

Respectfully submitted,
Milbank, Tweed, Hadley & McCloy LLP



May 14, 2001

Michael N. Nitabach, Ph.D.
Reg. No.: 47,344

Enclosures

Milbank, Tweed, Hadley & McCloy LLP
1 Chase Manhattan Plaza
New York, NY 10005-1413

(212) 530-5000 / (212) 530-5219 (facsimile)
NY2:#4411575